4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2023-D-1909]

Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act--Compliance Policies; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled "Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act--Compliance Policies." This guidance describes FDA's compliance policies regarding enforcement of requirements for the interoperable, electronic, package level product tracing (referred to as enhanced drug distribution security requirements) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) that will go into effect on November 27, 2023. FDA believes the compliance policies outlined in this guidance will help supply chain stakeholders, particularly trading partners, by accommodating the additional time that may be needed to continue to develop and refine appropriate systems and processes to conduct interoperable, electronic tracing at the package level, to achieve robust supply chain security under the Drug Supply Chain Security Act (DSCSA) while helping ensure continued patient access to prescription drugs.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-D-1909 for "Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act--Compliance Policies." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001

New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Pepinsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4258, Silver Spring, MD 20993-0002, 301-796-3130, email: drugtrackandtrace@fda.hhs.gov; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act--Compliance Policies." This guidance describes FDA's compliance policies regarding enforcement of requirements for the interoperable, electronic, package level product tracing (referred to as enhanced drug distribution security requirements) under section 582(g)(1) of the FD&C Act (21 U.S.C. 360eee-1(g)(1)) that will go into effect on November 27, 2023. FDA believes that these compliance policies will facilitate the continued use of product tracing and verification methods currently being used while accommodating the additional time that may be needed by trading partners to continue to develop and refine the systems and processes for such activities required under section 582(g)(1) of the FD&C Act.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (21

CFR 10.115(g)(2)). The Agency made this determination because the Agency needs to communicate its compliance policy in a timely manner and provide stakeholders notice of the compliance policy ahead of the effective date of the enhanced distribution security requirements. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA's GGP regulation and the Agency will consider all comments received and determine whether revisions to the guidance document are appropriate.

The DSCSA, enacted on November 27, 2013, outlines critical steps for building an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs as they are distributed within the United States. Since the enactment of DSCSA, FDA and trading partners have been preparing for the implementation of the enhanced drug distribution security requirements imposed by section 582(g)(1) of the FD&C Act. Trading partners are continuing to work to have the necessary systems and processes in place in anticipation of the November 27, 2023, effective date for these requirements. While trading partners have the obligation to comply with section 582 requirements, including for enhanced drug distribution security, there are other stakeholders involved and affected, including but not limited to: solution providers, standards organizations, trade and professional organizations, state authorities, and other Federal authorities.

FDA understands that collaboration and alignment among trading partners and other stakeholders throughout the supply chain are critical for achieving interoperability under the DSCSA. FDA has heard from stakeholders, including a broad representation of trading partners, about concerns regarding trading partner readiness and the need for clarity and flexibility to ensure trading partners can continue to move product through the supply chain when the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act take effect. Most recently, at a virtual public meeting on DSCSA Implementation and Readiness Efforts for 2023 held on December 7 and 8, 2022 (87 FR 67047, November 7, 2022), stakeholders indicated that trading partners throughout the supply chain are at different stages of

readiness, with some trading partners being further behind not only in terms of understanding their obligations under section 582(g)(1) of the FD&C Act, but also being aware of the time and resources necessary to meet those obligations. Stakeholders also expressed a need for clarity with respect to treatment of product that is already in the supply chain on November 27, 2023, and the need for flexibility when the requirements under section 582(g)(1) take effect, to minimize potential disruptions in the supply chain. In addition, stakeholders are experiencing challenges with predicting and planning for the possible volume of requests for product tracing information from Federal and State authorities and other trading partners, and the resources needed to respond to such requests, in accordance with section 582(g)(1) of the FD&C Act.

While FDA generally expects trading partners to have the systems and processes in place to meet the enhanced drug distribution security requirements of section 582(g)(1) as of November 27, 2023, we recognize that some technical and operational issues, including issues involving trading partners and other affected stakeholders, may not be fully resolved by that time. The Agency also understands that additional time beyond November 27, 2023, may be needed for systems to stabilize and be fully interoperable for accurate, secure, and timely electronic data exchange. This guidance is intended to provide clarity and flexibility to trading partners to help ensure continued patient access to prescription drugs as the supply chain transitions to the interoperable, electronic product tracing at the package level under the DSCSA. The compliance policies in this guidance can help trading partners throughout the supply chain implement the requirements under section 582(g)(1) of the FD&C Act by accommodating the additional time that may be needed to implement, troubleshoot, and mature their systems and processes while supporting the continued availability of products to patients.

The guidance represents the current thinking of FDA on "Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act--Compliance Policies." It does not establish any rights for any person and is not binding on FDA

or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.[1]

II. Paperwork Reduction Act

FDA concludes that this guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

Dated: August 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-18359 Filed: 8/25/2023 8:45 am; Publication Date: 8/28/2023]

[1] The Office of the Federal Register has published this document under the category "Rules and Regulations" pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the Federal Register does not affect the content or intent of the document. See 1 CFR 5.1(c).